

April 3, 2014

Attention: FDA further extends expiration dates of DuoDote auto-injector lots manufactured by Meridian Medical Technologies

Dear Wholesaler, Healthcare Professional and Emergency Personnel:

Please see the attached Alert Notice from the U.S. Food and Drug Administration (FDA) from March 28, 2014, regarding further extension of expiration dates of DuoDote auto-injector lots.

The lots of DuoDote that are specified in the alert can be used for up to two years past the originally labeled expiration date, provided the products have been and continue to be stored under labeled storage conditions.

The table below is an updated list of DuoDote auto-injector lots and new use dates. This new list includes each of the lots listed in FDA's September 5, 2013, DuoDote memorandum and December 24, 2013, Alert Notice, and also includes one new lot, 0AE792.

Lot Number	Manufacturer's Original Expiry Date	New Use Date (up to 2 years beyond manufacturer's original expiry date)
9AE307	March 31, 2013	March 31, 2015
9AE356	March 31, 2013	March 31, 2015
9AE545	March 31, 2013	March 31, 2015
9AE548	May 31, 2013	May 31, 2015
9AE636	May 31, 2013	May 31, 2015
9AE645	June 30, 2013	June 30, 2015
9AE835	September 30, 2013	September 30, 2015
0AE158	December 31, 2013	December 31, 2015
0AE159	December 31, 2013	December 31, 2015
0AE287	February 28, 2014	February 28, 2016
0AE458	April 30, 2014	April 30, 2016
0AE500	May 31, 2014	May 31, 2016
0AE501	May 31, 2014	May 31, 2016
0AE792	September 30, 2014	September 30, 2016

If replacement DuoDote product becomes available during the two-year extension period, then it is expected that the DuoDote lots in this updated table will be replaced and properly disposed of as soon as possible.

If you require further information about the attached FDA Alert Notice, please contact Brad Leissa at brad.leissa@fda.hhs.gov or Brooke Courtney at brooke.courtney@fda.hhs.gov.

If you require further information about the auto-injectors mentioned in the FDA Alert Notice, please contact Meridian's customer service office at 1-866-478-6277.

Sincerely,

A handwritten signature in black ink, appearing to read 'TH', with a large, sweeping flourish extending to the right.

Tom Handel
SVP-Commercial Pharmaceuticals

Recommendations to wholesalers

If you further distributed any of the above listed products, please communicate this information to those accounts immediately.

FDA further extends expiration dates of DuoDote auto-injector lots manufactured by Meridian Medical Technologies

Certain lots of DuoDote can be used for two years beyond the labeled expiration date

[03/28/2014] FDA is alerting health care professionals and emergency responders that certain lots of DuoDote auto-injectors, manufactured by Meridian Medical Technologies, can be used for up to two years beyond the manufacturer’s labeled expiration date. To help ensure patient safety, these products should have been — and should continue to be — stored under their labeled storage conditions.

This updates FDA’s December 2013 alert, which notified health care professionals and emergency responders of a one-year extension of the labeled expiration date of certain lots of DuoDote auto-injectors. The table below is an updated list of DuoDote auto-injector lots and new use dates. This new list includes each of the lots listed in FDA’s [September 5, 2013, DuoDote memorandum](#) and [December 24, 2013, posting](#), and also includes one new lot, OAE792.

DuoDote auto-injector lots eligible for use up to two years beyond the manufacturer’s labeled expiration date (updated March 28, 2014)

Lot Number	Manufacturer’s Original Expiry Date	New Use Date (up to 2 years beyond manufacturer’s original expiry date)
9AE307	March 31, 2013	March 31, 2015
9AE356	March 31, 2013	March 31, 2015
9AE545	March 31, 2013	March 31, 2015
9AE548	May 31, 2013	May 31, 2015
9AE636	May 31, 2013	May 31, 2015
9AE645	June 30, 2013	June 30, 2015
9AE835	September 30, 2013	September 30, 2015
OAE158	December 31, 2013	December 31, 2015
OAE159	December 31, 2013	December 31, 2015
OAE287	February 28, 2014	February 28, 2016
OAE458	April 30, 2014	April 30, 2016
OAE500	May 31, 2014	May 31, 2016
OAE501	May 31, 2014	May 31, 2016
OAE792	September 30, 2014	September 30, 2016

If replacement DuoDote product becomes available during the two-year extension period, then it is expected that the DuoDote lots in this updated table will be replaced and properly disposed of as soon as possible.

FDA is not requiring or recommending that the identified lots be relabeled with the new use date. Please contact Brad Leissa at brad.leissa@fda.hhs.gov or Brooke Courtney at brooke.courtney@fda.hhs.gov with questions regarding this table.